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Substitute for form 1449A/PTO

# **SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 1 of 1

## **Complete if Known**

Application Number	10/735,408
Filing Date	December 12, 2003
First Named Inventor	Storer <i>et al.</i>
Group Art Unit	1623
Examiner Name	Unassigned
Attorney Docket Number	06171.105101 IDX 1024

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## **U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages/Relevant Figures Appear	T <sup>6</sup>
		Number	Kind Code (if known)				
CK	AA	6,891,036	B2	Inalco S.p.A.	05-10-2005		

## **FOREIGN PATENT DOCUMENTS**

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		Office <sup>3</sup>	Number	Kind Code <sup>2</sup> (if known)				

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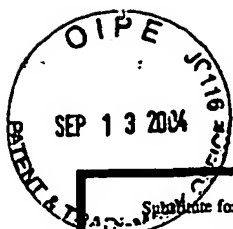
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CK	AB	ŽEMLIČKA, J., <i>et al.</i> , "Substrate specificity of ribosomal peptidyltransferase. Effect of modification in the heterocyclic, carbohydrate and amino acid moiety of 2'(3')-O-L-phenyladenosine," <i>Biochemistry</i> , 14(24):5239-5249 (02 December 1975).	
CK	AC	ŽEMLIČKA, J., <i>et al.</i> , "Aminoacyl derivatives of nucleosides, nucleotides, and polynucleotides. VIII. The preparation of 2'(3')-O-L-phenylalanyluridine, -cytidine, -adenosine, -inosine, -guanosine and 2'-deoxy-3'-O-L-phenylalanyladenosine," <i>Collection Czechoslov., Chem. Commun.</i> , 43(13):3755-3767 (1969).	

Examiner Signature	G. Krizian	Date Considered	12/5/06
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		Number	Kind Code (if known)				
GC	AA	3,798,209	A	Wilkowski, <i>et al.</i>	03-19-1974		
	AB	RE29,835		Witkowski <i>et al.</i>	11-14-1978		
	AC	4,294,766	A	Schmidt <i>et al.</i>	10-13-1981		
	AD	4,522,811	A	Eppstein <i>et al.</i>	06-11-1985		
	AE	4,952,740	A	Juge <i>et al.</i>	08-28-1990		
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	AAA	2003/0050229	A1	Sommadossi <i>et al.</i>	03-13-2003		
GC	AAB	2003/0060400	A1	LaColla <i>et al.</i>	03-27-2003		

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<b>Filing Date</b>	<b>December 12, 2003</b>
<b>First Named Inventor</b>	<b>Storer <i>et al.</i></b>
<b>Group Art Unit</b>	<b>1623</b>
<b>Examiner Name</b>	<b>Unassigned</b>
<b>Attorney Docket Number</b>	<b>06171.105101 IDX 1024</b>

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		Office <sup>2</sup>	Number	Kind Code <sup>3</sup> (if known)				
EC	CA	WO	01/92282	A2&3	Novirio (Idenix); Univ. ... Cagliari	06-12-2001		
	CB	WO	01/96353	A2	Novirio Pharm. (Idenix); C.N.R.S.	21-20-2001		
	CC	WO	02/057287	A2	Merck; Isis Pharmaceuticals	07-25-2002		
	CD	WO	02/057425	A2	Merck; Isis Pharmaceuticals	07-25-2002		
	CE	WO	02/18404	A2	Hoffman-La Roche AG	03-07-2002		
	CF	WO	02/32414	A2	Schering Corporation	04-25-2002		
	CG	WO	02/32920	A2	Pharmasset	04-25-2002		
	CH	WO	02/48165	A2	Pharmasset	06-20-2002		
	CI	WO	03/024461	A1	Schering Corporation	03-27-2003		
	CJ	WO	04/003138	A2	Merck & Co., Isis Pharmaceutical	01-08-2004		
EC	CK	WO	04/009020	A2	Merck & Co., Isis Pharmaceutical	01-29-2004		

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EC	CL	BAGINSKI, S. G. <i>et al.</i> , "Mechanism of action of a pestivirus antiviral compound," <i>PNAS USA</i> , 97(14): 7981-7986 (2000).	
	CM	BATTAGLIA, A.M. <i>et al.</i> , "Combination Therapy with Interferon and Ribavirin in the Treatment of Chronic Hepatitis C Infection", <i>Ann. Pharmacother.</i> , 34:487-494 (2000).	
	CN	BEIGELMAN, L.N., <i>et al.</i> , "Functionally complete analogues of nucleosides. The use of D-glucose for the synthesis of 2'-C-methyl-D-ribose derivatives and related nucleosides," <i>Bioorg. Khim.</i> , 12(10):1359-1365 (1986). <i>Abstract in English at p. 1365.</i> <i>Considered English Abstract</i>	Abstract in English at p. 1365
	CO	BEIGELMAN, L.N., <i>et al.</i> , "New synthesis of 2'-C-methylnucleosides starting from D-glucose and D-ribose," <i>Carbohydrate Research</i> , 166:219-232 (1987).	
	CP	BENZARIA, S., <i>et al.</i> , "Synthesis of potential prodrugs of $\beta$ -L-dC, a potent and selective anti-HBV agent," <i>Antiviral Res.</i> , 50:A79 (2001).	
	CQ	BERENGUER, M. <i>et al.</i> , "Hepatitis C virus in the transplant setting", <i>Antivir. Ther.</i> , 3 (Suppl 3):125-136 (1998).	
	CR	BERMAN, E. <i>et al.</i> , "Synergistic cytotoxic effect of azidothymidine and recombinant interferon alpha on normal human bone marrow progenitor cells," <i>Blood</i> , 74(4):1281-1286 (1989)	
EC	CS	BHAT <i>et al.</i> (Oral Session V, Hepatitis C Virus, Flaviviridae, 2003 (Oral Session V, Hepatitis C Virus, Flaviviridae; 16 <sup>th</sup> International Conference on Antiviral Research (April 27, 2003, Savannah, Ga.); p A75).	

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pk	DA	BROWNE, M.J., <i>et al.</i> , "2',3'-didehydro-3'-deoxythymidine (d4T) in patients with AIDS or AIDS-Related Complex: A Phase I trial," <i>J. Infect. Dis.</i> , 167(1):21-29 (1993).	
	DB	BRYANT, M.L., <i>et al.</i> , "Antiviral L-nucleosides specific for hepatitis B virus infection," <i>Antimicrobial Agents and Chemotherapy</i> , 45(1):229-235 (January 2001).	
	DC	CAVELIER, F., <i>et al.</i> , "Studies of selective Boc removal in the presence of silyl ethers," <i>Tetrahedron Letters</i> , 37:5131-5134 (1996).	
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	DI	De LOMBAERT, S., <i>et al.</i> , "N-Phosphonomethyl dipeptides and their phosphonate prodrugs, a new generation of neutral endopeptidase (NEP, EC 3.4.24.11) inhibitors," <i>J. Med. Chem.</i> , 37:498-511 (1994).	
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	DK	DYMOCK, B.W., <i>et al.</i> , "Review: Novel approaches to the treatment of hepatitis C virus infection," <i>Antiviral Chemistry &amp; Chemotherapy</i> , 11(2):79-95 (2000).	
	DL	ELDRUP <i>et al.</i> (Oral Session V, Hepatitis C Virus, Flaviviridae; 16 <sup>th</sup> International Conference on Antiviral Research (April 27, 2003, Savannah, Ga.).	
	DM	FARKAS, J., <i>et al.</i> , "Nucleic acid components and their analogues. XCIV. Synthesis of 6-amino-9-(1-deoxy- $\beta$ -D-psicofuranosyl)purine", <i>Collect. Czech. Chem. Commun.</i> 32:2663-2667 (1967).	
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pk	DO	FARQUHAR, D., <i>et al.</i> , "Synthesis and biological evaluation of neutral derivatives of 3-fluoro-2'-deoxyuridine 5'-phosphate," <i>J. Med. Chem.</i> 26: 1153 (1983);	

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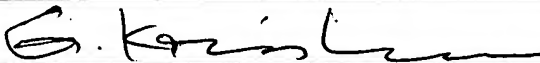
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CK	EA	FARQUHAR, D., <i>et al.</i> , "Synthesis and biological evaluation of 9-[5'-(2-oxo-1,3,2-oxazaphosphorinan-2-yl)-β-D-arabinosyl]adenine and 9-[5'-(2-oxo-1,3,2-dioxazaphosphorinan-2-yl)-β-D-arabinosyl]adenine: Potential neutral precursors of 9-[β-D-arabinofuranosyl]adenine 5'-monophosphate," <i>J. Med. Chem.</i> 28:1358-1381 (1985).	
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	EG	HARRY-O'KURU, R.E., J.M. Smith, and M.S. Wolfe, "A short, flexible route toward 2'-C-branched ribonucleosides," <i>J. Org. Chem.</i> 62, 1754-1759 (1997). (Scheme 11).	
	EH	HOSTETLER, K.Y., <i>et al.</i> , "Synthesis and antiretroviral activity of phospholipids analogs of azidothymidine and other antiviral nucleosides," <i>J. Biol. Chem.</i> , 265:6112-6117 (April 15, 1990)	
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	EJ	HUNSTON, R.N., <i>et al.</i> , "Synthesis and biological properties of some cyclic phosphotriesters derived from 2'-deoxy-5-fluorouridine," <i>J. Med. Chem.</i> 27:440-444 (1984).	
	EK	JONES, G. H., and MOFFATT, J. G., "[55] Oxidation of carbohydrates by the sulfoxide-carbodiimide and related methods: Oxidation with dicyclohexylcarbodiimide-DMSO, diisopropylcarbodiimide-DMSO, acetic anhydride-DMSO, and phosphorus pentaoxide-DMSO," <i>Methods in Carbohydrate Chemistry</i> ; Whisler, R. L. and Moffatt, J. L. Eds; Academic Press: New York, 1972; 315-322	
	EL	JONES, G. H., <i>et al.</i> , "4'-substituted nucleosides. 5. Hydroxymethylation of nucleoside 5'-aldehydes," <i>J. Org. Chem.</i> , 44:1309-1317 (1979).	
CK	EM	KEMPE, T., <i>et al.</i> , "Selective 2'-benzoylation at the cis 2',3'-diols of protected ribonucleosides. New solid phase synthesis of RNA and DNA-RNA mixtures," <i>Nucleic Acids Res.</i> , 10(21):6695-6714 (November 11, 1982).	

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Application Number	10/735,408
Filing Date	December 12, 2003
First Named Inventor	Storer et al.
Group Art Unit	1623
Examiner Name	Unassigned
Attorney Docket Number	06171.105101 IDX 1024

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**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>4</sup>
GK	FA	KERR, S.G., et al., "N <sup>4</sup> -(dialkylamino)methylene derivatives of 2'-deoxycytidine and arabinocytidine: physicochemical studies for potential prodrug applications," <i>J. Pharm. Sci.</i> , 83(4):582-586 (April 1994).	
	FB	KHAMNEI, S., "Neighboring group catalysis in the design of nucleotide prodrugs," <i>J. Med. Chem.</i> , 39:4109-4115 (1996).	
	FC	KILIANI, H., "Ueber Saccharin und Saccharinsäure," <i>Chemische Berichte</i> , 15:2953 (1882). In <i>German. Partial translation in English at pp. 43-44 of the SOWDEN reference.</i>	see SOWDEN
	FD	KOHN, P., et al., "A new method for the synthesis of furanose derivatives of aldohexoses," <i>J. Am. Chem. Soc.</i> , 87(23):5475-5480 (December 5, 1965).	
	FE	KUCERA, L.S., et al., "Novel membrane-interactive ether lipid analogs that inhibit infectious HIV-1 production and induce defective virus formation," <i>AIDS Res. Hum. Retro Viruses</i> , 6:491-501 (1990).	
	FF	KURTZBERG J., et al., "Differential toxicity of carbovir and AZT to human bone marrow hematopoietic progenitor cells in vitro," <i>Exp. Hematol.</i> , 18(10):1094-1096 (1990).	
	FG	LEONARD, N. J., et al., "5-Amino-5-deoxyribose derivatives. Synthesis and use in the preparation of "reversed" nucleosides" <i>J. Heterocycl. Chem.</i> , 3:485-489 (December 1966).	
	FH	LERZA, R., et al., "In vitro synergistic inhibition of human bone marrow hemopoietic progenitor growth by a 3'-azido-3'-deoxy-thymidine, 2',3'-dideoxycytidine combination," <i>Exp. Hematol.</i> , 25(3):252-255 (1997).	
	FI	LEWIS, W., et al., "Zidovudine induces molecular, biochemical, and ultrastructural changes in rat skeletal muscle mitochondria," <i>J. Clin. Invest.</i> , 89(4):1354-1360 (1992).	
	FJ	LEWIS, L. D., et al., "Ultrastructural changes associated with reduced mitochondrial DNA and impaired mitochondrial function in the presence of 2'3'-dideoxycytidine," <i>Antimicrob. Agents Chemother.</i> , 36(9):2061-2065 (1992).	
	FK	LEWIS, W., et al., "Fialuridine and its metabolites inhibit DNA polymerase $\gamma$ at sites of multiple adjacent analog incorporation, decrease mtDNA abundance, and cause mitochondrial structural defects in cultured hepatoblasts," <i>Proceedings of the National Academy of Sciences, USA</i> , 93(8): 3592-7 (1996).	
	FL	LI, N.-S., et al., "2'-C-branched ribonucleosides. 2. Synthesis of 2'-C- $\beta$ -trifluoromethyl pyrimidine ribonucleosides," <i>Organic Letters</i> , 3(7):1025-1028 (2001).	
	FM	LOHMANN V., et al., "Biochemical and kinetic analyses of NS5B RNA-dependent RNA polymerase of the Hepatitis C virus," <i>Virology</i> , 249, 108-118 (1998).	
GK	FN	LOPEZ-HERRERA, F.J., et al., "A new synthesis of 2-C-methyl-D-ribo-1,4-lactone and the C-(C-13 fragment of methynolide," <i>J. Carbohydrate Chemistry</i> , 13(5):767-775 (1994).	

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**INFORMATION DISCLOSURE  
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OK	GA	LOPEZ APARICIO, F.J., <i>et al.</i> , "Synthesis of saccharinic acid derivatives," <i>Carbohydrate Res.</i> , 129:99 (1984).	
	GB	LUH, T.-Y., <i>et al.</i> , "A convenient method for the selective esterification of amino-alcohols," <i>Synthetic Communications</i> , 8(5):327-333 (1978).	
	GC	McCORMICK, J., <i>et al.</i> , "Structure and total synthesis of HF-7, a neuroactive glyconucleoside disulfate from the funnel-web spider <i>Hololena curta</i> ," <i>J. Am. Chem. Soc.</i> , 121(24), 5661-5664 (1999).	
	GD	MCKENZIE, R., <i>et al.</i> , "Hepatic failure and lactic acidosis due to fialuridine (FIAU), an investigational nucleoside analogue for chronic hepatitis B," <i>N. Engl. J. Med.</i> , 333(17):1099-1105 (1995).	
	GE	MEDINA, D. J., <i>et al.</i> , "Comparison of mitochondrial morphology, mitochondrial DNA content, and cell viability in cultured cells treated with three anti-Human Immunodeficiency Virus dideoxynucleosides," <i>Antimicrob. Agents Chemother.</i> , 38(8):1824-8 (1994).	
	GF	MEIER, C., <i>et al.</i> , "Cyclic saligenyl phosphotriesters of 2',3'-dideoxy-2',3'-dideoxythymidine (d4T) - A new pro-nucleic approach," <i>Bioorganic &amp; Med. Chem. Letters</i> 7(2):99-104 (1997).	
	GG	MEYER, R.B., Jr., <i>et al.</i> , "2'-O-Acyl-6-thioinosine cyclic 3',5'-phosphates as prodrugs of thioinosinic acid," <i>J. Med. Chem.</i> 22: 811-815 (1979).	
	GH	NEIDLEIN, R., <i>et al.</i> , "Mild preparation of 1-benzylolxyiminoalkylphosphonic dichlorides: Application to the synthesis of cyclic phosphonic diesters and cyclic monoester amides," <i>Heterocycles</i> 35:1185-1203 (1993).	
	GI	NOVÁK, J.J.K. & SORM, F., "Nucleic acid components and their analogues. CXX. 2-C-methyl-D-ribose and its derivatives," <i>Collection Czechoslov. Chem. Commun.</i> , 34:857-866 (1969).	
	GJ	NOVÁK, J.J.K., "Chiroptical properties of 2-methyl-1,4-lactones; revised absolute configuration of 2-deoxy-2-C-methyl-erythro-D-pentono-1,4-lactones," <i>Collection Czechoslov. Chem. Commun.</i> , 39:869-882 (1974).	
	GK	NUTT, R.F., <i>et al.</i> , "Branched-chain sugar nucleosides. III. 3'-C-methyladenine," <i>J. Org. Chem.</i> , 33:1789-1795 (1968).	
	GL	OLSEN, <i>et al.</i> (Oral Session V, Hepatitis C Virus, Flaviviridae; 16 <sup>th</sup> International Conference on Antiviral Research (April 27, 2003, Savannah, Ga.) p A76).	
	GM	PAN-ZHOU, X-R., <i>et al.</i> , "Differential effects of antiretroviral nucleoside analogs on mitochondrial function in HepG2 cells," <i>Antimicrob. Agents Chemother.</i> 44:496-503 (2000).	
	GN	PIANTADOSI, C., <i>et al.</i> , "Synthesis and evaluation of novel ether lipid nucleoside conjugates for anti-HIV-1 activity," <i>J. Med. Chem.</i> 34:1408-1414 (1991).	
OK	GO	PIERRA, C., <i>et al.</i> , "Comparative studies of selected potential prodrugs of $\beta$ -L-dC, a potent and selective anti-HBV agent," <i>Antiviral Res.</i> , 50:A79 (2001), Abstract no. 138.	

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OK	HA	RICHMAN, D.D., <i>et al.</i> , "The toxicity of azidothymidine (AZT) in the treatment of patients with AIDS and AIDS-Related Complex," <i>N. Engl. J. Med.</i> , 317(4):192-197 (1987).	
	HB	SCHEIBLER, C., "Ueber das Saccharin und die Saccharinsäure," <i>Chemische Berichte</i> , 13:2212-2217 (1880). <i>In German.</i>	
	HC	SOMMADOSSI J-P, <i>et al.</i> , "Comparison of cytotoxicity of the (-)- and (+)- enantiomer of 2',3'-dideoxy-3'-thiacytidine in normal human bone marrow progenitor cells," <i>Biochemical Pharmacology</i> 44(10):1921-1925 (1992).	
	HD	SOMMADOSSI J-P., <i>et al.</i> , "Toxicity of 3'-azido-3'-deoxythymidine and 9-(1,3-dihydroxy-2-propoxymethyl)guanine for normal human hematopoietic progenitor cells in vitro," <i>Antimicrobial Agents and Chemotherapy</i> , 31:452-454 (1987).	
	HE	SOWDEN, J., "The Saccharinic Acids," <i>Adv. Carbohydrate Chem.</i> , 12:43-46 (1957).	
	HF	STANDRING, D.N., <i>et al.</i> , "Antiviral beta-L-nucleosides specific for hepatitis B virus infection," <i>Antiviral Chem. &amp; Chemother.</i> , 12 (Suppl. 1):119-129 (2001).	
	HG	STARRETT, J.E.Jr., <i>et al.</i> , "Synthesis, oral bioavailability determination, and <i>in vitro</i> evaluation of prodrugs of the antiviral agents 9-(2-(phosphonomethoxy)ethyl]adenine (PMEA)," <i>J. Med. Chem.</i> 37: 1857-1864 (1994).	
	HH	TANG, X.-Q., <i>et al.</i> , "2'-C-branched ribonucleosides: Synthesis of the phosphoramidite derivatives of 2'-C- $\beta$ -methylcytidine and their incorporation into oligonucleotides," <i>J. Org. Chem.</i> , 64(3):747-754 (1999).	
	HI	WALTON, E., <i>et al.</i> , "Branched-chain sugar nucleosides. A new type of biologically active nucleoside," <i>J. Am. Chem. Soc.</i> , 88(19):4524-4525 (October 5, 1966).	
	HJ	WEINBERG, R.S., <i>et al.</i> , "Effect of antiviral drugs and hematopoietic growth factors on <i>in vitro</i> erythropoiesis," <i>Mt. Sinai J. Med.</i> 1998;65(1):5-13.	
	HK	WHISTLER, R.L., and BeMILLER, J.N., "[118] 'a'-D-Glucosaccharino-1,4-lactone," <i>Methods in Carbohydrate Chemistry</i> , 2:484-485 (1963).	
	HL	YARCHOAN, R., <i>et al.</i> "Long-term toxicity / activity profile of 2',3'-dideoxyinosine in AIDS or AIDS-related complex," <i>The Lancet</i> , 336(8714):526-529 (1990).	
	HM	YOSHIDA Y, <i>et al.</i> , "Reversal of azidothymidine-induced bone marrow suppression by 2',3'-dideoxythymidine as studied by hemopoietic clonal culture," <i>AIDS Res. Hum. Retroviruses</i> , 6(7):929-932 (1990).	
OK	HN	ZON, G., "Cyclophosphamide Analogues," Chapter 4 in <i>Progress in Medicinal Chemistry</i> , Vol. 19, G.P. Ellis and G.B. West, Eds., pp. 205-246 (1982).	

Not available, but also not needed based on description in Sowden article:

*Justus Liebigs Annalen Chemie*, 213:361 (1883). KILIANI, H.,

OK	BK	WO	0024355	A1	Smith & Nephew Kinetic	05-04-2000
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